

**COOK, ALEX, McFARRON, MANZO,
CUMMINGS & MEHLER, LTD.**

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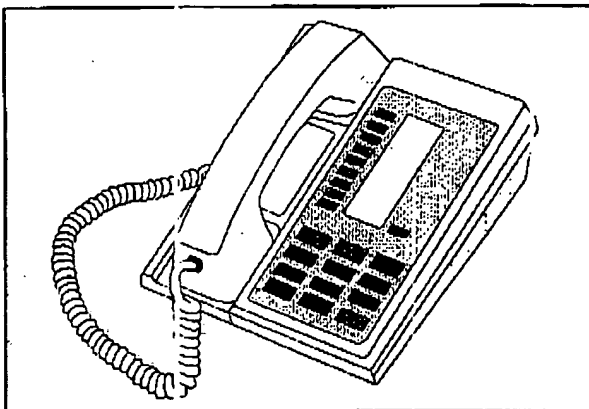
JUN 30 2005

Date: June 30, 2005

Client: 3360

To: Examiner Thurman K. Page

From: Raymond M. Mehler



Telecopier Number: 703-872-9306

Main Phone Number: 571-272-0602

City the Message is Being Faxed to: Alexandria VA

Remarks:

Mr. Page, here is a the Declaration you had requested for 10/135,821.

Ray Mehler

Please contact us if you have any problems receiving this message.

Our telecopier number is 312-236-8176.

Our telephone number is 312-236-8500, Direct 312-334-8536.

My e-mail address is: rmehler@cammc.com.

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JUN 30 2005

Attorney Docket No. IFT-5657A-1 (3360-0023.02) PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:)
Werling et al.)
Serial No: 10/035,821)
Filed: October 19, 2001)
Art Unit: 1615)
Confirmation No.: 2470)
Examiners: Thurman K. Page)
Simon J. Oh)
For: METHOD FOR PREPARING)
SUBMICRON SUSPENSIONS)
WITH POLYMORPH CONTROL)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION

Sir:

We, Jane Werling, James E. Kipp, Rajaram Sriram and Mark J. Doty aver as follows:

1. We each are over the age of twenty-one years, and we are the joint inventors of U.S. Patent Application Serial No. 10/035,821, filed October 19, 2001.
2. We have reviewed the claims of this application and believe that the claimed invention was conceived prior to January 7, 2000 and we diligently worked on this project until reduction to practice. All of these activities took place in the United States.

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3. As evidence of this, attached are laboratory notebook pages with dates redacted. The laboratory notebook pages are not necessarily the earliest data of conception of the claimed invention and do not represent the results of an exhaustive search for evidence of the earliest date of conception or reduction to practice.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true, and further, we acknowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under \$1001 of Title 18 of the United States Code and may jeopardize the validity of the application or any patent issuing thereon.

Date: 6/30/05

Jane Werling
Jane Werling

Date: _____

James E. Kipp
James E. Kipp

Date: _____

Rajaram Sriram
Rajaram Sriram

Date: _____

Mark J. Doty
Mark J. Doty

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Date: _____

Date: 6/27/05

Date: _____

Date: _____

Jane Werling

James E. Kipp

Rajaram Sriram

Mark J. Doty

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06/24/2005 11:06 FAX

COOK ALEX MCFARRON MANZO

0003

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We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true, and further, we acknowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and may jeopardize the validity of the application or any patent issuing thereon.

Date: _____

Jane Worling

Date: _____

James L. King

Date: June 26, 2005

Rajaram Sriram

Date: _____

Mark J. Doty

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Date: _____

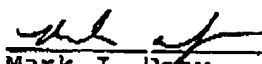
Jane Werling

Date: _____

James E. Kipp

Date: _____

Rajaram Bhiram

Date: 6/27/05
Mark J. Doty

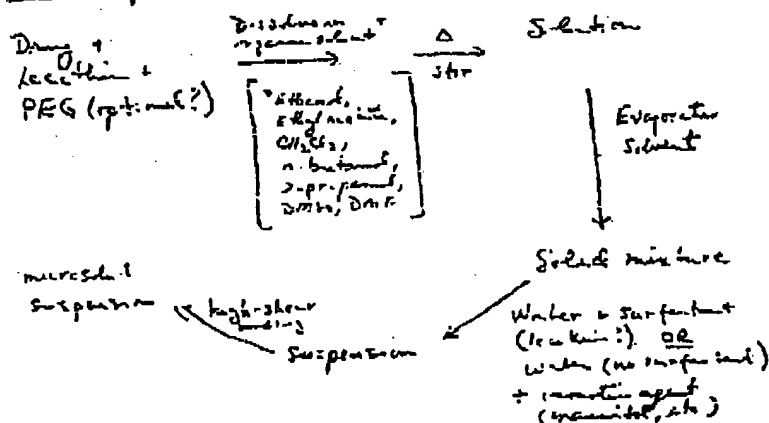
BOOK NO. 20744 - 39

Solid Dispersion of Prednisolone - Preliminary

PPM 170

Notebook

Purpose: Test the hypothesis that we can make more potent (or maybe particle size in a micro-suspension - by first preparing a solid dispersion of the drug in a matrix such as PEG (polyethylene glycol) and/or phosphatidylcholine (or lecithin). The solid is then resuspended in an aqueous solvent (water + surfactant). Hopefully, high shear mixing (stirring; homogenization?) will cause breakdown of the solid to form micro-crystals (or micro-sized homogenized drug) in suspension.

General procedure.

I will first attempt to prepare a 1% prednisolone suspension using a 5% (w/w) solid dispersion of drug + lecithin (or egg phosphatidylcholine). This solid will be ~~the~~ dispersed in an aqueous medium (water + emulsifier). Call this formulation FORMULATION 1

J S Kijne

Mal Inf

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BOOK NO. 20813 - 60

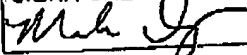
TITLE pH-precipitation of Lactic Acid Prior to HomogenizationFirst Page No. 1Page No. 1

Purpose: Note an idea. Use pH-induced ^{micro}precipitation of Intracmazole prior to homogenization to reduce ^{micro}particle size. Use lactic acid to solubilize the drug. (See Chem. Pharm. Bull, 46(8), 1333-1334 (1998).

Lactic Acid → pH → Homogenization → Add → Stabilize → Store
+ Drug or other means change or other means or other mechanical means surfactant(s)

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SIGNATURE



DATE

REVIEW

DATE

SYSTEM OF INVENTION

** TOTAL PAGE 03 **